

## REMARKS

Claims 16-31 were pending in the present application.

Claim 16 has been amended and claims 26-30 cancelled, leaving claims 16-25 and 31 for consideration in the present amendment. Support for the amendment to claim 16 can at least be found in paragraph 80 of the corresponding published application, US Pat. Pub. No. 2006/0257334. No new matter is believed to have been entered by way of amendment.

Favorable reconsideration and allowance of the claims are respectfully requested in view of the foregoing amendments and the following remarks.

### Provisional Nonstatutory Double Patenting Rejections

Claims 16 and 22 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14 and 20 of the copending application published as Application Publication No. 2007/0105746 A1. 03/29/2010 Office Action, paragraph spanning pages 2 and 3.

Applicants thank the Examiner for pointing out the potential obviousness-type double patenting issue between the claims of the present application and those of the copending application published as Application Publication No. 2007/0105746 A1. In view of the possibility that claims in the cited application or the present application will be further amended before allowance, Applicants will defer responding to this provisional rejection until claims in the reference application are allowed, claims in the present application are otherwise allowable, and it is determined whether this provisional rejection becomes an actual rejection.

Applicants also respectfully note that the present application was filed before the cited application. Accordingly, the present provisional rejection should be withdrawn if it becomes the sole remaining rejection. See MPEP 804(I)(B)(1) ("If a 'provisional'

nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer.”).

Obviousness Rejections over Vanlerberghe

A. Claims 16 and 19-31 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Vanlerberghe et al. (US Patent 5985255).

B. Claims 17-18 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Vanlerberghe et al. (US Patent 5985255) in view of Dahms (US Patent 5747012).

Applicants respectfully traverse these rejections.

Vanlerberghe is generally directed to a composition containing a wax microdispersion. The wax microdispersion includes the use of a cationic emulsifying agent. The process for forming the wax microdispersion can be characterized as a phase inversion technique, which is widely used in latex paint manufacturing.

Dahms is generally directed to compositions for topical application.

For an obviousness rejection to be proper, the Examiner must meet the burden of establishing a *prima facie* case of obviousness. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). Establishing a *prima facie* case of obviousness requires that all limitations of the claim be taught or suggested by the prior art. *See, e.g., CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003); *In re Royka*, 490 F.2d 981, 985 (C.C.P.A. 1974).

A *prima facie* case of obviousness has not been established because there is no teaching or even suggestion of Applicants’ claimed process comprising, *inter alia*, stirring the phase B into an aqueous phase A, which may comprise an emulsifier, at a

temperature above the melting or softening point of the active compound vehicle, the weight ratio of phase B to phase A being 1:5 to 5:1, without high-pressure homogenization, to form a -preferably gellike - lyotropic liquid-crystalline mixed phase. As claimed, the water phase functions as a continuous phase from the beginning to the end of the process. There is no phase inversion. On the contrary, Vanlerberghe is clearly directed to a phase inversion process and employs a cationic emulsifying agent in its phase inversion process. Dahms fails to compensate for the deficiencies of Vanlerberghe. As noted by Vanlerberghe:

It is also known that it is possible to obtain microemulsions with specific oils and microdispersions with certain waxes, which are stable and, for the latter, dilutable indefinitely in water, without aggregation or sedimentation of suspended particles. The wax microdispersions are obtained by **melting the wax in the presence of an anionic or non-ionic surfactant**, and optionally with some water, then with **gradual addition of hot water with stirring**. The intermediate formation of a **water-in-oil type emulsion** is observed, followed by a **phase inversion with the final attainment of an oil-in-water type emulsion**. On cooling a stable microdispersion of solid colloidal wax particles is obtained; ...

(Vanlerberghe, Col. 1, ll. 32-44, emphasis added)

Vanlerberghe uses the above phase inversion technique as further exemplified by Vanlerberghe in its specification, its examples, and claims.

**The compositions according to the present invention are obtained by the formation under heat of a microemulsion.** More accurately, these compositions are obtained by a process that is mainly characterized by the fact that the mixture of wax and emulsifier is heated to which optionally is added an oil and/or liposoluble substances, at a temperature which is greater than the melting temperature of the mixture and not greater than 100° C., optionally in the presence of a portion of the water, up to complete melting. **Water** or the remainder of the water, brought to a temperature that is at least equal to the temperature at which the mixture of wax and emulsifier is heated, **is gradually added by stirring, until there is formed a wax microemulsion in a continuous aqueous phase**. On cooling the microemulsion to ambient temperature a wax microdispersion is formed.

(Vanlerberghe at Col. 4, ll. 49-65, emphasis added.)

The wax and the cationic emulsifying agent are admixed and the mixture is heated to about 90° C. by slowly stirring in order to obtain good homogenization. **Water, that has previously been heated to 90°C, is then incorporated by stirring and a microemulsion is thus obtained.** The temperature of the wax microemulsion is returned to ambient temperature at which point a microdispersion is formed.

(Vanlerberghe at Col. 6, ll. 18-25, emphasis added.)

1. In a process for preparing a microdispersion of solid wax particles in an aqueous vehicle by melting wax in the presence of a surfactant and optionally a portion of water, and **progressively adding hot water with stirring until an oil-in-water type emulsion is formed,** and cooling to obtain a stable microdispersion of solid colloidal wax particles, the improvement comprising using a surfactant consisting of a quaternary ammonium cationic surfactant having an HLB value ranging from 11 to 16, as said surfactant.

3. A process for preparing a composition comprising a stable microdispersion of solid particles in a single phase aqueous vehicle, wherein said solid particles consist essentially of a mixture of:

at least one wax in an amount ranging from 0.1 to 40% by weight relative to the weight of the composition,

a surfactant consisting of at least one quaternary ammonium cationic surfactant having an HLB value ranging from 11 to 16, in an amount ranging from 0.01 to 25% by weight relative to the composition,

optionally at least one liposoluble active ingredient in an amount up to 30% by weight relative to the weight of said at least one wax,

optionally at least one oil in an amount up to 30% relative to the weight of said at least one wax, and

optionally at least one amphiphilic non wax-emulsifying compound in an amount up to 30% by weight relative to the weight of said at least one wax,

said mixture having an end melting point greater than 50° C. and lower than 100° C,

and wherein said composition is free of anionic and non ionic surfactants,

said process consisting essentially of:

mixing said at least one wax, said cationic surfactant and optionally said oil, said amphiphilic compound and/or said liposoluble active ingredient,

heating the obtained mixture, optionally in the presence of a portion of water, at a heating temperature lower than 100° C., up to complete melting,

**progressively adding, with stirring, water,** or the remainder of water, heated to said heating temperature, **until** there is formed a wax microemulsion in a continuous aqueous phase whereby cooling said microemulsion to ambient temperature results in a microdispersion of solid particles having a size less than 0.5  $\mu\text{m}$ .

(Vanlerberghe, claims 1, 3, emphasis added.)

In view of the foregoing disclosures, Vanlerberghe's phase inversion technique first utilizes an oil phase as a continuous phase to which water is slowly added until at some point there is phase inversion and water then becomes the continuous phase. If conditions are "*right*" during the phase invention, the oil phase disperses to form particles of relatively small sizes. The crossing of the phase inversion point is the critical point which has to be watched carefully and usually is done extremely slowly. Otherwise, the formed particles will not be of uniform and small size, and consequently may not be stable. It is noted that it is generally considered difficult to control the quality of the product by phase inversion.

In contrast, the claimed process does not include phase inversion. According to the claimed invention, as defined in step b of claim 1, the water phase A is added to phase B (wax, polymer- or lipid based) in the defined weight range. In the invention, the water phase is the continuous phase from the beginning until the end of the process and phase inversion does not occur. Accordingly, Vanlerberghe's phase inversion process is markedly different from Applicants claimed process that does not utilize phase inversion.

In view of the foregoing, a *prima facie* case of obviousness has not been established and the rejection should be withdrawn.

Applicants therefore respectfully request the reconsideration and withdrawal of the rejection of claims 23-25, 30, and 31 under 35 U.S.C. § 103(a) over Speiser in view of De Vringer.

It is believed that the foregoing remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and allowance is respectfully requested.

It is believed that all the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper.

If there are any additional charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130 maintained by Applicants' Attorneys.

Respectfully submitted,

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